

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant : Frank R. Miele, et al.

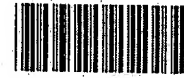
App. No. : 09/815,982

Filed : March 22, 2001

For : **METHOD AND APPARATUS FOR  
THE NONINVASIVE ASSESSMENT  
OF HEMODYNAMIC PARAMETERS  
INCLUDING BLOOD VESSEL  
LOCATION**

Examiner : Unknown

Group Art Unit: 3736



27299

PATENT, TRADEMARK OFFICE

I hereby certify that this correspondence  
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addressed to: Assistant Commissioner  
for Patents, Washington, D.C. 20231, on

January 17, 2002

(Date)

  
Robert F. Gazdzinski, Reg. No. 39,990**TRANSMITTAL LETTER**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Enclosed for filing in the above-identified application are:

1. Information Disclosure Statement (3 pages) and a copy of the referenced International Search Report;
2. Form PTO-1449 (4 pages) including ninety-one (91) references; and,
3. Return prepaid postcard.

Respectfully submitted,

GAZDZINSKI &amp; ASSOCIATES

Dated: January 17, 2002

By:   
Robert F. Gazdzinski, Esq.  
Registration No. 39,990  
Attorney of Record  
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San Diego, CA 92123  
(858) 505-1166

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VWAVE.001CP2



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**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Enclosed is a copy of form PTO-1449 listing ninety-one (91) references. A portion of the enclosed references were previously submitted in prior application, Serial No. 09/342,549, filed June 29, 1999 entitled "Method and Apparatus for the Noninvasive Determination of Arterial Blood Pressure" (VWAVE.001A) from which the above-referenced pending application claims priority. Thus, pursuant to 37 C.F.R. § 1.98(d) copies of the listed references are not required; however, applicant has enclosed copies of the references herewith for the Examiner's convenience.

**App. No.** : 09/815,982  
**Filed** : March 22, 2001

Additionally, pursuant to 37 C.F.R. 1.98, the enclosed form PTO-1449 lists four issued patents which are assigned to the assignee hereof and potentially related to subject matter of the subject named application.

Pursuant to § 609A(3) of the Manual of Patent Examining Procedure, a copy of the International Search Report is attached for your reference. Applicant respectfully submits that such International Search Report satisfies the requirement for a concise explanation relating to EPO 0 299 827 A1 and DE 42 18 319 A1, which are not provided in the English Language.

Also, the enclosed form PTO-1449 lists Patent No. EP 0 595 666 B1. The subject patent is written in French; Applicant accordingly submits herewith what is believed to be the English language (U.S. Patent) equivalent, namely U.S. Patent No. 5,479,928, pursuant to § 609A(3) of the Manual of Patent Examining Procedure.

With regard to Patent No. 0 284 095 B1, a German patent listed on the enclosed PTO-1449 form, please refer to the Summary of Content and Concise Explanation of Reference and Translation of Figures attached directly to the patent, which are submitted for the Examiner's review pursuant to § 609A(3) of the Manual of Patent Examining Procedure.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, it is requested that the undersigned be contacted for payment of the fee as set forth in 37 C.F.R. § 1.17(p).

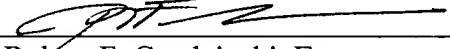
**App. No.** : 09/815,982  
**Filed** : March 22, 2001

Pursuant to 37 C.F.R. § 1.97(g) and (h), Applicant makes no representation that a search has been made or that the information cited is considered to be material to patentability. Additionally, inclusion on this list is not an admission that any of the cited documents are prior art in this application. Further, Applicant makes no representation regarding the completeness of this list or that better art does not exist.

Respectfully submitted,

GAZDZINSKI & ASSOCIATES

Dated: January 17, 2002

By:   
Robert F. Gazdzinski, Esq.  
Registration No. 39,990  
Attorney of Record  
3914 Murphy Canyon Road, Suite A232  
San Diego, CA 92123  
(858) 505-1166

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

VWAVE.001CP2

APPLICATION NO.

09/815,982

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT

Frank R. Miele, et al.

FILING DATE

March 22, 2001

GROUP

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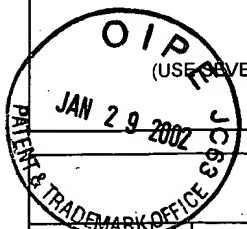
## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME                | CLASS | SUBCLASS | FILING DATE<br>(IF APPROPRIATE) |
|---------------------|----|-----------------|----------|---------------------|-------|----------|---------------------------------|
|                     | 1  | 3,527,197       | 09/08/70 | Ware, et al.        |       |          |                                 |
|                     | 2  | 3,601,120       | 08/24/71 | Massie, et al.      |       |          |                                 |
|                     | 3  | 3,617,993       | 11/02/71 | Massie, et al.      |       |          |                                 |
|                     | 4  | 3,663,932       | 05/16/72 | Mount, et al.       |       |          |                                 |
|                     | 5  | 3,791,378       | 02/12/74 | Hochbert, et al.    |       |          |                                 |
|                     | 6  | 3,885,551       | 05/27/75 | Massie              |       |          |                                 |
|                     | 7  | 4,109,647       | 08/29/78 | Stern, et al.       |       |          |                                 |
|                     | 8  | 4,127,114       | 11/28/78 | Bretscher           |       |          |                                 |
|                     | 9  | 4,154,231       | 05/15/79 | Russell             |       |          |                                 |
|                     | 10 | 4,239,047       | 12/16/80 | Griggs, III, et al. |       |          |                                 |
|                     | 11 | 4,249,540       | 02/10/81 | Koyama, et al.      |       |          |                                 |
|                     | 12 | 4,349,034       | 09/14/82 | Ramsey, III         |       |          |                                 |
|                     | 13 | 4,476,875       | 10/16/84 | Nilsson, et al.     |       |          |                                 |
|                     | 14 | 4,566,462       | 01/28/86 | Janssen             |       |          |                                 |
|                     | 15 | 4,590,948       | 05/27/86 | Nilsson             |       |          |                                 |
|                     | 16 | 4,596,254       | 06/24/86 | Adrian, et al.      |       |          |                                 |
|                     | 17 | 4,651,747       | 03/24/87 | Link                |       |          |                                 |
|                     | 18 | 4,660,564       | 04/28/87 | Benthin, et al.     |       |          |                                 |
|                     | 19 | 4,719,923       | 01/19/88 | Hartwell, et al.    |       |          |                                 |
|                     | 20 | 4,754,761       | 07/05/88 | Ramsey, III, et al. |       |          |                                 |
|                     | 21 | 4,771,792       | 09/20/88 | Seale               |       |          |                                 |
|                     | 22 | 4,867,170       | 09/19/89 | Takahashi           |       |          |                                 |
|                     | 23 | 4,869,261       | 09/26/89 | Penaz               |       |          |                                 |
|                     | 24 | 4,901,733       | 02/20/90 | Kaida, et al.       |       |          |                                 |
|                     | 25 | 4,924,871       | 05/15/90 | Honeyager           |       |          |                                 |
|                     | 26 | 4,960,128       | 10/02/90 | Gordon, et al.      |       |          |                                 |
|                     | 27 | 5,030,956       | 07/09/91 | Murphy              |       |          |                                 |
|                     | 28 | 5,072,733       | 12/17/91 | Spector, et al.     |       |          |                                 |
|                     | 29 | 5,094,244       | 03/10/92 | Callahan, et al.    |       |          |                                 |

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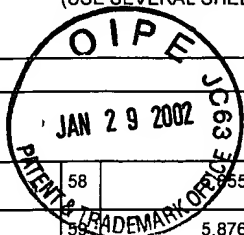
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|---------------------------------------------------------------------------------------------------|------------------------------------------------------------|-------------------------------------|-------------------------------|
| FORM PTO-1449                                                                                     | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO.<br>VWAVE.001CP2    | APPLICATION NO.<br>09/815,982 |
| <b>INFORMATION DISCLOSURE STATEMENT<br/>BY APPLICANT</b><br><br>(USE SEVERAL SHEETS IF NECESSARY) |                                                            | APPLICANT<br>Frank R. Miele, et al. |                               |
|                                                                                                   |                                                            | FILING DATE<br>March 22, 2001       | GROUP<br>3736                 |

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE      | NAME     | CLASS               | SUBCLASS | FILING DATE<br>(IF APPROPRIATE) |
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|                     | 30              | 5,119,822 | 06/09/92 | Niwa                |          |                                 |
|                     | 31              | 5,158,091 | 10/27/92 | Butterfield, et al. |          |                                 |
|                     | 32              | 5,163,438 | 11/17/92 | Gordon, et al.      |          |                                 |
|                     | 33              | 5,170,796 | 12/15/92 | Kobayashi           |          |                                 |
|                     | 34              | 5,238,000 | 08/24/93 | Niwa                |          |                                 |
|                     | 35              | 5,240,007 | 08/31/93 | Pytel, et al.       |          |                                 |
|                     | 36              | 5,261,412 | 11/16/93 | Butterfield, et al. |          |                                 |
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|                     | 38              | 5,327,893 | 07/12/94 | Michael Savic       |          |                                 |
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|                     | 40              | 5,409,010 | 04/25/95 | Kirk Beach, et al.  |          |                                 |
|                     | 41              | 5,439,001 | 08/08/95 | Butterfield, et al. |          |                                 |
|                     | 42              | 5,450,852 | 09/19/95 | Archibald, et al.   |          |                                 |
|                     | 43              | 5,467,771 | 11/21/95 | Narimatsu, et al.   |          |                                 |
|                     | 44              | 5,479,928 | 01/02/96 | Cathignol, et al.   |          |                                 |
|                     | 45              | 5,494,043 | 02/27/96 | O'Sullivan, et al.  |          |                                 |
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|                     | 47              | 5,551,434 | 09/03/96 | Kazuhiro Iinuma     |          |                                 |
|                     | 48              | 5,590,649 | 01/07/97 | Caro, et al.        |          |                                 |
|                     | 49              | 5,617,867 | 04/08/97 | Butterfield, et al. |          |                                 |
|                     | 50              | 5,634,467 | 06/03/97 | Nevo                |          |                                 |
|                     | 51              | 5,642,733 | 07/01/97 | Archibald, et al.   |          |                                 |
|                     | 52              | 5,649,542 | 07/22/97 | Archibald, et al.   |          |                                 |
|                     | 53              | 5,749,364 | 05/12/98 | Sliwa, et al.       |          |                                 |
|                     | 54              | 5,785,654 | 07/28/98 | Iinuma, et al.      |          |                                 |
|                     | 55              | 5,832,924 | 11/10/98 | Archibald, et al.   |          |                                 |
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| FORM PTO-1449                                                                                     | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO.<br>VWAVE.001CP2    | APPLICATION NO.<br>09/815,982 |
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| 59 | 5,876,346    | 03/02/99 | Corso               |  |  |  |
| 60 | 5,895,359    | 04/20/99 | Peel, III           |  |  |  |
| 61 | 5,904,654    | 05/18/99 | Wohltmann, et al.   |  |  |  |
| 62 | 5,908,027    | 06/01/99 | Butterfield, et al. |  |  |  |
| 63 | 5,916,180    | 06/29/99 | Cundari, et al.     |  |  |  |
| 64 | 5,964,711    | 10/12/99 | Voss, et al.        |  |  |  |
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| 66 | 6,176,831    | 01/23/01 | Voss, et al.        |  |  |  |
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| 68 | 6,258,031 B1 | 07/10/01 | Sunagawa, et al.    |  |  |  |
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| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER                                                                                                                    | DATE       | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|---------------------|----|------------------------------------------------------------------------------------------------------------------------------------|------------|---------|-------|----------|-------------|----|
|                     |    |                                                                                                                                    |            |         |       |          | YES         | NO |
|                     | 70 | EP 284 095 B1<br>Including Summary of Content<br>and Concise Explanation of<br>Reference and Exhibit 1 -<br>Translation of Figures | March 1988 | Europe  |       |          |             |    |
|                     | 71 | 0 342 249 A1                                                                                                                       | May 1988   | Europe  |       |          |             |    |
|                     | 72 | EP 0299 827 A1                                                                                                                     | June 1988  | Europe  |       |          |             |    |
|                     | 73 | EP 0595 666 B1                                                                                                                     | Sept. 1993 | Europe  |       |          |             |    |
|                     | 74 | 0 603 666 A2                                                                                                                       | Dec. 1993  | Europe  |       |          |             |    |
|                     | 75 | EP 0818 176 A1                                                                                                                     | July 1996  | Europe  |       |          |             |    |
|                     | 76 | DE 4218319 A1                                                                                                                      | June 1992  | Germany |       |          |             |    |
|                     | 77 | WO 84 00290                                                                                                                        | Feb. 1984  | PCT     |       |          |             |    |
|                     | 78 | WO 92 07508                                                                                                                        | May 1992   | PCT     |       |          |             |    |
|                     | 79 | WO 95/00074                                                                                                                        | Jan. 1995  | PCT     |       |          |             |    |
|                     | 80 | WO 95 13014                                                                                                                        | May 1995   | PCT     |       |          |             |    |
|                     | 81 | WO 98 25511 A                                                                                                                      | June 1998  | PCT     |       |          |             |    |

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| FORM PTO-1449                                                                                     | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO.<br>VWAVE.001CP2    | APPLICATION NO.<br>09/815,982 |
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|                                                                                                   |                                                            | FILING DATE<br>March 22, 2001       | GROUP<br>3736                 |

| EXAMINER<br>INITIAL | OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)                                                                                                                                           |
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| 82                  | Drzewiecki, G. (1995) "Noninvasive Assessment of Arterial Blood Pressure and Mechanics," The Biomedical Engineering Handbook CRC Press, Boca Raton, FL, pp. 1196-1211.                                           |
| 83                  | Boashash, B., et al. (1987) "An Efficient Real-Time Implementation of the Wigner-Ville Distribution," IEEE Trans ASSP 35:1611-1618.                                                                              |
| 84                  | Drzewiecki, G.M., et al. (1985) Generalization of the Transmural Pressure-Area Relation for the Femoral Artery," 7 <sup>th</sup> Annual IEEE EMBS Conference 507.                                                |
| 85                  | Hoeks, A.P.G., et al. (1985) Transcutaneous Detection of Relative Changes in Artery Diameter," Ultrasound in Med and Bio 11:51-59.                                                                               |
| 86                  | Carson, E.R., et al. (1983) "The Mathematical Modeling of Metabolic and Endocrine Systems: Model Formulation, Identification, and Validation," John Wiley & Sons, NY, pp. 185-189.                               |
| 87                  | Anderson, E.A., et al. (1989) "Flow-Mediated and Reflex Changes in Large Peripheral Artery Tone in Humans," Circulation 79:93-100.                                                                               |
| 88                  | Hartley, C.J., et al. (1991) "An Ultrasonic Method for Measuring Tissue Displacement: Technical Details and Validation for Measuring Myocardial Thickening," IEEE Trans Biomed, 38:735-747.                      |
| 89                  | Cariou, Alain, et al. (1998) "Noninvasive Cardiac Output Monitoring by Aortic Blood Flow Determination: Evaluation of the Sometec Cynemo-3000 System," Critical Care Medicine, Vol. 26, No. 12, pp. 2066-2072    |
| 90                  | Advertisement for HemoSonic™ 100 by Arrow International – licensed under U.S. Patent 5,479,928 listed above                                                                                                      |
| 91                  | Application Serial No. 09/815,080 entitled "Method and Apparatus For Assessing Hemodynamic Parameters within the Circulatory System of a Living Subject," filed March 22, 2001 – Attorney Docket No. VWAVE.003P1 |
|                     |                                                                                                                                                                                                                  |
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| EXAMINER                                                                                                                                                                                                                                 | DATE CONSIDERED |
| *EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT. |                 |